UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,179	12/03/2003	Herbert W. Harris	18184-0003US	8872

23973 7590 03/19/2009

DRINKER BIDDLE & REATH
ATTN: INTELLECTUAL PROPERTY GROUP
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

EXAMINER	
SOROUSH, LAYLA	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
03/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,179	HARRIS ET AL.	
	Examiner	Art Unit	
	LAYLA SOROUSH	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *13-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 29, 2008 has been entered. The original restriction election is carried over from the response to the office action mailed on February 27, 2007.

Claims 1-12 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation "substantially free" renders the claim vague and indefinite because it is unclear whether the claims are free of or not free of the corresponding (s)-enantiomer.

.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Korosi et al. (US Pat No. 4,423,044).

Korosi et al. discloses a pharmaceutical composition containing an active ingredient a 3,4-Dihydro-5H-2,3-benzodiazepine derivatives of the formula (I) and pharmaceutically acceptable acid addition salts thereof, wherein R represents a phenyl group optionally carrying one or two substituents selected from the group consisting of halogen, hydroxy, C1-4 alkoxy and benzyloxy; a furyl or a thienyl group. R1 stands for a hydrogen atom or a C1-4 alkyl group, R2 and R3 each represent hydrogen atom, C1-4 alkoxy, C4-7 cycloalkoxy or benzyloxy group together with a conventional inert, non-toxic, solid or liquid carrier and/or additive. Hence, the compound of formula I wherein the R represents a phenyl group carrying two substitiuents selected from a hydroxyl, a C1 alkoxy, R1 stands for a c2 alkyl group, R2 and R3 represents two C1 alkoxy groups (col 9 claim 1 and col 10 claim 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korosi et al. (US Pat No. 4,423,044) as applied to claims 1 and 12 above.

Korosi et al. fails to teach (R) or (S)- 1-(3-hydroxy-4-methoxyphenyl)-4-methyl-5-ethyl-7,8- dimethoxy-5H-2,3-benzodiazepine.

The difference between the present claims and prior art is that applicants claim the R and S isomer whereas the prior art discloses the racemate. However, it is generally known in the art that normally, one of the enantiomers of a racemate would possess a disproportionate amount of the desired biological activity. This would motivate one of ordinary skill to isolate the separate enantiomers in order to determine which of the two is most effective for the desired purpose. In addition, the isomer/enantiomer of a racemate is prima facie obvious. In re Adamson, 125 USPQ 233 (1960).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is

shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6864251 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention herein is drawn to a pharmaceutical composition comprising a pharmaceutically acceptable carrier and 1-(3-hydroxy-4-methoxyphenyl)-4-methyl-5-ethyl-7,8- dimethoxy-5H-2,3-benzodiazepine, or a pharmaceutically acceptable salt thereof whereas the prior art teaches a method of treating a individual afflicted with an inflammatory disorder mediated by LTB.sub.4 comprising administering to said individual an effective amount of at least one compound inclusive of 1-(3-hydroxy-4-methoxyphenyl)-4-methyl-5-ethyl-7,8- dimethoxy-5H-2,3-benzodiazepine, or a pharmaceutically acceptable salt thereof.

It would have been obvious to a skilled artisan that the identical compound would be useful as a pharmaceutically acceptable compound as claimed.

Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent Application No. 10/727940. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention herein is drawn to a pharmaceutical composition comprising a pharmaceutically acceptable carrier and 1-(3-hydroxy-4-methoxyphenyl)-4-methyl-5-ethyl-7,8- dimethoxy-5H-2,3-benzodiazepine, or a

pharmaceutically acceptable salt thereof whereas the prior art teaches a method of treating an individual afflicted with an inflammatory disorder comprising administering to said individual an effective amount of at least one compound inclusive of 1-(3-hydroxy-4-methoxyphenyl)-4-methyl-5-ethyl-7,8- dimethoxy-5H-2,3-benzodiazepine, or a pharmaceutically acceptable salt thereof.

It would have been obvious to a skilled artisan that the identical compound would be useful as a pharmaceutically acceptable compound as claimed.

Response to Arguments

Applicant's arguments filed December 29, 2008 have been fully considered. The response to the arguments is as discussed below:

With respect to Applicant's arguments regarding the limitation "substantially free", Examiner states that substantially free renders the claim vague and indefinite because it is unclear whether the claims are free of or not free of the corresponding (s)-enantiomer.

Applicant argues that Korosi et al. does not disclose the compound 1-(3-hydroxy-4-methoxyphenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-benzodiazepine by name or structure. Examiner respectfully reiterates that Korosi et al. discloses in claims 1 and 9 an identical core structure and substituants that are so small in number that one could

readily envisage the claimed species. Examiner maintains the position that Korosi et al. anticipates the claimed compound.

Applicant's argument over claims 2-11 rejections depends on the validity of the previous arguments which were not found persuasive.

The terminal disclaimer filed by Applicant has not been approved because the attorney is not of record. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome a provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. (See 37 CFR 1.130(b)).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617